

INFORMATION  
DISCLOSURE  
STATEMENTAPR 9 7 2006  
U.S. PATENT AND TRADEMARK OFFICE

Atty. Docket No.:	110.01980101	Serial No.:	10/532,039
Applicant(s):	STEER et al.	Confirmation No.:	8552
Application Filing Date:	April 21, 2005	Group:	1614
371(c) Date:	September 22, 2005	Information Disclosure Statement mailed:	
Information Disclosure Statement mailed:			April 5, 2006

## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		5,656,725	08/12/97	Chittenden et al.			
		5,672,603	09/30/97	Nakai et al.			
		6,544,972 B1	04/08/03	Steer et al.			
		6,555,141 B1	04/29/03	Corson et al.			
		2003 0044413A1	03/06/03	Steer et al.			
		10/549,867	09/22/05	Steer et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation
							Yes No
	✓	WO 99/15179	04/01/99	PCT			
	✓	WO 2004/043342 A2	05/27/04	PCT			
	✓	WO 2004/096123 A2 & A3	11/11/04	PCT			
	✓	PCT/US06/04394	02/08/06	Steer et al.			

## OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
	✓	Adjei et al., "Cathepsin B Protease Activity But Not Interleukin 1 $\beta$ -Converting Enzyme (ICE) Proteases Contributes to Camptothecin-Induced Apoptosis in a Human Hepatocellular Carcinoma Cell Line," AASLD Abstract 481, <i>Hepatology</i> , 1996;24(4 Part 2):247A.
	✓	Adjei et al., "Selective Induction of Apoptosis in Hep 3B Cells by Topoisomerase I Inhibitors: Evidence for a Protease-dependent Pathway that Does Not Activate Cysteine Protease P32," <i>J. Clin. Invest.</i> , 1996 Dec;98(11): 2588-2596.

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	✓	Adjei et al., "Selective Induction of Apoptosis In A Human Hepatocellular Carcinoma (HCC) Cell Line by the Topoisomerase I Inhibitor Camptothecin," Abstract, <i>Gastroenterology</i> , 1996 Apr;110(4):A483.
	✓	Alexander et al., "Aphasia after left hemispheric intracerebral hemorrhage," <i>Neurology</i> , 1980 Nov;30:1193-1202.
	✓	American Heart Association, <i>Heart and Stroke Facts</i> , 1991, Bethesda, MD, pgs. 7-11.
	✓	Auer et al., "Endoscopic surgery versus medical treatment for spontaneous intracerebral hematoma: a randomized study," <i>J. Neurosurg.</i> , 1989;70:530-535.
	✓	Barnaby, "Stroke Intervention," <i>Emerg. Med. Clin. North Amer.</i> , 1990 May; 8(2):267-280.
	✓	Beaufay et al., "Analytical Study of Microsomes and Isolated Subcellular Membranes from Rat Liver I. Biochemical Methods," <i>J. Cell Biol.</i> , 1974;61:188-200.
	✓	Beers et al., Eds., <i>The Merck Manual of Diagnosis and Therapy</i> , 17 <sup>th</sup> Ed., 1999:1452-1476.
	✓	Benedetti et al., "Subcellular changes and apoptosis induced by ethanol in rat liver," <i>J. Hepatology</i> , 1988 Apr;6(2):137-143.
	✓	Benz et al., "Effect of taurooursodeoxycholic acid on bile-acid-induced apoptosis and cytolysis in rat hepatocytes," <i>J. Hepat.</i> , 1998 Jan;28(1):99-106.
	✓	Bernardi, "Modulation of the Mitochondrial Cyclosporin A-sensitive Permeability Transition Pore by the Proton Electrochemical Gradient," <i>J. Biol. Chem.</i> , 1992 May 5;267(13):8834-8839.
	✓	Bogousslavsky et al., "The Lausanne Stroke Registry: Analysis of 1,000 Consecutive Patients With First Stroke," <i>Stroke</i> , 1988 Sep;19(9):1083-1092.
	✓	Boise et al., "bcl-x, a bcl-2-Related Gene That Functions as a Dominant Regulator of Apoptotic Cell Death," <i>Cell</i> , 1993 Aug 27;74(4):597-608.

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	✓	Botla et al., "Ursodeoxycholate Inhibits the Mitochondrial Membrane Permeability Transition (MMPT) Induced by Glycochenodeoxycholate: A Mechanism for Ursodeoxycholate Cytoprotection?" AASLD Abstract 316, <i>Hepatology</i> , 1994;20(4)Part 2:175A.
	✓	Botla et al., "Ursodeoxycholate (UDCA) Inhibits the Mitochondrial Membrane Permeability Transition Induced by Glycochenodeoxycholate: A Mechanism of UDCA Cytoprotection," <i>J. Pharmacol. Exp. Ther.</i> , 1995 Feb;272(2):930-938.
	✓	Bouscaren et al., "Alteration of cAMP-mediated hormonal responsiveness by bile acids in cells of nonhepatic origin," <i>Am. J. Physiol.</i> , 1995 Jun;268(6):G908-G916.
	✓	Bouscaren et al., "Ursodeoxycholic acid inhibits glucagon-induced cAMP formation in hamster hepatocytes: a role for PKC," <i>Am. J. Physiol.</i> , Feb 1995;268(2):G300-G310.
	✓	Broderick et al., "The Risk of Subarachnoid and Intracerebral Hemorrhages in Blacks as Compared with Whites," <i>N. Engl. J. Med.</i> , 1992 Mar 12;326(11):733-736.
	✓	Bullock et al., "Intracerebral Hemorrhage in a Primate Model: Effect on Regional Cerebral Blood Flow," <i>Surg. Neurol.</i> , 1988 Feb;29(2):101-107.
	✓	Calmus et al., "Differential Effects of Chenodeoxycholic and Ursodeoxycholic Acids on Interleukin 1, Interleukin 6 and Tumor Necrosis Factor- $\alpha$ Production by Monocytes," <i>Hepatology</i> , 1992;16(3):719-723.
	✓	Caplan et al., "Intracerebral hemorrhage: An update," <i>Geriatrics</i> , May 1978; 33(5):42-52.
	✓	Caplan et al., "Intracerebral Hemorrhage," <i>Stroke: A Clinical Approach</i> , Stoneham, MA, 1986:261-292.
	✓	Carter et al., "Intracellular hydrogen peroxide and superoxide anion detection in endothelial cells," <i>J. Leukocyte Biol.</i> , 1994 Feb;55(2):253-258.

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	✓	Castro et al., "The Bile Acid Tauroursodeoxycholic Acid Modulates Phosphorylation and Translocation of Bad via Phosphatidylinositol 3-Kinase in Glutamate-Induced Apoptosis of Rat Cortical Neurons," <i>J. Pharm. Exp. Ther.</i> , 2004 Nov;311(2):845-852.
	✓	Cathcart et al., "Detection of Picomole Levels of Hydroperoxides Using a Fluorescent Dichlorofluorescein Assay," <i>Anal. Biochem.</i> , 1983;134:111-116.
	✓	Chazouillères et al., "Ursodeoxycholic acid for primary sclerosing cholangitis," <i>J. Hepatology</i> , 1990 Jul;11(1):120-123.
	✓	Cheng et al., "Caspase Inhibitor Affords Neuroprotection with Delayed Administration in a Rat Model of Neonatal Hypoxic-Ischemic Brain Injury," <i>J. Clin. Invest.</i> , May 1998;101(9):1992-1999.
	✓	Chesney et al., "Collagenase-Induced Intrastriatal Hemorrhage in Rats Results in Long-term Locomotor Deficits," <i>Stroke</i> , 1995 Feb;26(2):312-316.
	✓	Choi, "Ischemia-induced neuronal apoptosis," <i>Curr. Opin. Neurobiol.</i> , 1996 Oct;6(5):667-672.
	✓	Columbano, "Cell Death: Current Difficulties in Discriminating Apoptosis From Necrosis in the Context of Pathological Processes In Vivo," <i>J. Cell. Biochem.</i> , 1995;58:181-190.
	✓	Cooper, "Delayed Traumatic Intracerebral Hemorrhage," <i>Neurosurg. Clin. North Amer.</i> , 1992 Jul;3(3):659-665.
	✓	Datta et al., "Cellular survival: a play in three Akts," <i>Genes Dev.</i> , 1999 Nov 15; 13(22):2905-2927.
	✓	De Ryck, "Animal Models of Cerebral Stroke: Pharmacological Protection of Function," <i>Eur. Neurol.</i> , 1990 Feb;30(suppl 2):21-27.
	✓	Desjardins et al., "The Role of Apoptosis in Neurodegenerative Diseases," <i>Metab. Brain Dis.</i> , 1998 Jun;13(2):79-96.
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	✓	Dupourque et al., "Cytoplasmic and Mitochondrial Malate Dehydrogenases from Beef Kidney," <i>Methods Enzymol.</i> , New York, NY, 1969;13:116-122.
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	✓	Earnest et al., "Chemoprevention of Azoxymethane-induced Colonic Carcinogenesis by Supplemental Dietary Ursodeoxycholic Acid," <i>Cancer Res.</i> , 1994 Oct 1;54(19):5071-5074.
	✓	Ekshyyan et al., "Apoptosis: A Key in Neurodegenerative Disorders," <i>Curr. Neurovasc. Res.</i> , 2004;1(4):355-371.
	✓	Endres et al., "Attenuation of Delayed Neuronal Death After Mild Focal Ischemia in Mice by Inhibition of the Caspase Family," <i>J. Cereb. Blood Flow Metab.</i> , 1998 Mar;18(3):238-247.
	✓	Fan et al., "Modulation of Retinoblastoma and Retinoblastoma-related Proteins in Regenerating Rat Liver and Primary Hepatocytes," <i>Cell Growth &amp; Differ.</i> , 1995 Nov;6(11):1463-1476.
	✓	Fan et al., "The Retinoblastoma Gene Product Inhibits TGF- $\beta$ 1 Induced Apoptosis in Primary Rat Hepatocytes and Human HuH-7 Hepatoma Cells," <i>Oncogene</i> , 1996 May 2;12(9):1909-1919.
	✓	Fan et al., "The Retinoblastoma Gene Product is a Negative Modulator of the Apoptotic Pathway," <i>Advan. Enzyme Regul.</i> , Tarrytown, NY, 1996;36:283-303.
	✓	Fan et al., "A Novel Link Between REC2, a DNA Recombinase, the Retinoblastoma Protein, and Apoptosis," <i>J. Biol. Chem.</i> , 1997 Aug 1;272(31):19413-19417.
	✓	Fan et al., "Regulation of Apoptosis-Associated Genes in the Regenerating Liver," <i>Semin. Liver Dis.</i> , New York, NY, 1998;18(2):123-140.

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	✓	Gong et al., "Intracerebral Hemorrhage-induced Neuronal Death," <i>Neurosurgery</i> , Apr. 2001 Apr;48(4):875-883.
	✓	Goodman and Gilman's, "The Pharmacological Basis of Therapeutics," Ninth Ed., New York, NY, 1996, pp. 506-517.
	✓	Guicciardi et al., "Ursodeoxycholic Acid Cytoprotection: Dancing with Death Receptors and Survival Pathways," <i>Hepatology</i> , 2002 Apr;35(4):971-973.
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	✓	Hanif et al., "Bile acids induce apoptosis in the colon of mice <i>in vivo</i> ," <i>Gastroenterology</i> , Abstract A526, 1996;110(4):156.
	✓	Hankey et al., "Surgery for Primary Intracerebral Hemorrhage: Is It Safe and Effective? A Systematic Review of Case Series and Randomized Trials," <i>Stroke</i> , 1997 Nov;28(11):2126-2132.
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	✓	Harnois et al., "BCL-2 is Overexpressed and Alters the Threshold for Apoptosis in a Cholangiocarcinoma Cell Line," <i>Gastroenterology</i> , Abstract, 1996 Apr; 110(4):A1205.
	✓	Herrera et al., "TGF $\beta$ -induced Growth Inhibition in Primary Fibroblasts Requires the Retinoblastoma Protein," <i>Mol. Biol. Cell</i> , 1996 Sep;7(9):1335-1342.

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	✓	Honig et al., "Apoptosis and Neurologic Disease," <i>Am. J. Med.</i> , 2000 Mar; 108(4):317-330.
	✓	Hortnagl et al., "Pathophysiological aspects of human neurodegenerative diseases," <i>Wien. Klin. Wochenschr.</i> , 1997;109(16):623-635.
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	✓	Ihle, "Cytokine receptor signalling," <i>Nature</i> , 1995 Oct 19;377(6550):591-594.
	✓	Jacobson et al., "Programmed cell death and Bcl-2 protection in the absence of a nucleus," <i>EMBO J.</i> , 1994;13(8):1899-1910.
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	✓	Kingman et al., "Experimental intracerebral mass: time-related effects on local cerebral blood flow," <i>J. Neurosurg.</i> , 1987 Nov;67:732-738.		

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	✓	Koba et al., "Correlation Between the Location of Hematoma and its Clinical Symptoms in the Lateral Type of Hypertensive Intracerebral Hemorrhage," <i>Stroke</i> , 1977 Sep-Oct;8(5):676-680.
	✓	Koga et al., "Nuclear DNA Fragmentation and Expression of Bcl-2 in Primary Biliary Cirrhosis," <i>Hepatology</i> , 1997 May;25(5):1077-1084.
	✓	Kren et al., "Differential Regulation of Multiple Gap Junction Transcripts and Proteins during Rat Liver Regeneration," <i>J. Cell Biol.</i> , 1993 Oct;123(1):707-718.
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	✓	Kurosawa et al., "Hepatocytes in the bile duct-ligated rat express Bcl-2," <i>Am. J. Physiol.</i> , 1997 Jun;272(6):G1587-G1593.
	✓	Kwo et al., "Ursodeoxycholate and its Conjugates Protect Against Glycodeoxycholate-Induced Apoptosis," <i>Hepatology</i> , AASLD Abstract 640, 1994 Oct;20(4 Part 2):256A.
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	✓	Yoshikawa et al., "Immunomodulatory Effects of Ursodeoxycholic Acid on Immune Responses," <i>Hepatology</i> , 1992;16(2):358-364.

<b>EXAMINER</b> /Sara Clark/ (03/17/2009)	<b>Date Considered</b> 03/17/2009
*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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<b>INFORMATION DISCLOSURE STATEMENT</b>	Atty. Docket No.: 110.01980101	Serial No.: 10/532,039
	Applicant(s): STEER et al.	Confirmation No.: 8552
	Application Filing Date: April 21, 2005 371(c) Date: September 22, 2005	Group: 1614
	Information Disclosure Statement mailed:	April 5, 2006

Examiner Initial	Copy Enclosed	Document Description
	✓	Yuan et al., "Apoptosis in the nervous system," <i>Nature</i> , 2000 Oct 12;407(6805): 802-809.
	✓	Zamzami et al., "Reduction in Mitochondrial Potential Constitutes an Early Irreversible Step of Programmed Lymphocyte Death in Vivo," <i>J. Exp. Med.</i> , 1995 May;181(5):1661-1672.

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